510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 06/12/2013

1. Submitter

	Submitter
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2. Submission Correspondent

LK Consulting Group USA, Inc.
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3. Device

- Trade Name: LipidPro® Lipid Profile and Glucose Measuring System
  LipidPro® Professional Lipid Profile and Glucose Measuring System
- Classification: Total cholesterol test system (21 CFR Part 862.1175)
  Lipoprotein test system (21 CFR Part 862.1475)
  Triglyceride test system (21 CFR Part 862.1705)
  Glucose test system (21 CFR Part 862.1345)
  Quality control material (21 CFR Part 862.1660)
- Product Code: CHH, LBR, JGY, NBW, CGA, JJX

4. Predicate Device:

(K090405) LipidPro™ System, LipidPro™ Total Cholesterol Control Solution, LipidPro™ HDL Cholesterol Control Solution, LipidPro™ Triglyceride Control Solution, LipidPro™ Glycose Control Solution

5. Description:

The LipidPro® / LipidPro® Professional Lipid Profile and Glucose Measuring System consist

of a meter, test strips, and control solutions. It combines measuring systems for total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol and triglyceride, and a blood glucose monitoring system into one convenient device.
The components are a meter, five types of test strips, and four types of control solutions. There are five types of the test strips which are for total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG), a lipid profile (which combines TC, HDL-C, and TG tests) and glucose test respectively. There are also four types of the control solutions for total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), triglyceride (TG) and glucose test respectively.

6. Indications for use:

• LipidPro® Lipid Profile and Glucose Measuring System

The LipidPro® Lipid Profile and Glucose Measuring System is intended for self testing (in home) and for testing outside the body (in vitro diagnostic use only). The LipidPro® Lipid Profile and Glucose Measuring System, which consists of a meter and test strips, measures total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG) and glucose in capillary whole blood. The LipidPro® Lipid Profile and Glucose Measuring System is intended to be used by a single patient and should not be shared.

The LipidPro® Total Cholesterol Test Strip, LipidPro® HDL-cholesterol Test Strip, LipidPro® Triglyceride Test Strip, LipidPro® Lipid Profile Test Strip, and LipidPro® Glucose Test Strip are for use with the LipidPro® Lipid Profile and Glucose Meter.
The LipidPro® Total Cholesterol Test Strip and the LipidPro® HDL-cholesterol Test Strip are used to measure total cholesterol (TC) and high density lipoprotein cholesterol (HDL-C) in capillary whole blood respectively and the measurements obtained are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid, and lipoprotein metabolism disorders. The LipidPro® Total Cholesterol Test Strip and LipidPro® HDL-cholesterol Test Strip measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. The LipidPro® Triglyceride Test Strip is used to measure triglyceride (TG) in capillary whole bloodandthe obtained measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism, or various endocrine disorders. Calculated LDL-cholesterol values are reported only when triglycerides are ≤ 350 mg/dL; when triglycerides are > 350 mg/dL, calculated LDL-cholesterol are not reported.
The LipidPro® Lipid Profile Test Strip is used to measure TC, HDL-C, and TG in capillary whole blood at the same time.
The LipidPro® Glucose Test Strip is for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients as an aid in the management of diabetes. Glucose measurement is not to be used for the diagnosis of or screening for diabetes and/or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

LipidPro® Total Cholesterol Control Solution, HDL-cholesterol Control Solution, Triglycerides Control Solution, and Glucose Control Solution are used to test the precision of the LipidPro® Lipid Profile and Glucose Measuring System and to detect systematic analytic deviations that may arise from reagent or analytical variation and they are for testing outside the body (in vitro diagnostic use only). LipidPro® Control Solutions are intended for use in home.

▪ LipidPro® Professional Lipid Profile and Glucose Measuring System

The LipidPro® Professional Lipid Profile and Glucose Measuring Systemis intended for multiple patient use in professional health care settings and for testing outside the body (in vitro diagnostic use only). The LipidPro® Professional Lipid Profile and Glucose Measuring System which consists of meter and test strips, measures total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG), and glucose in capillary whole blood. The LipidPro® Professional Lipid Profile and Glucose Measuring System should only be used with auto-disabling, single-use lancing device.

The LipidPro® Professional Total Cholesterol Test Strip, LipidPro® Professional HDL-cholesterol Test Strip, LipidPro® Professional Triglyceride Test Strip, LipidPro® Professional Lipid Profile Test Strip, and LipidPro® Professional Glucose Test Strip are for use with the LipidPro® Professional Lipid Profile and Glucose Meter.
The LipidPro® Professional Total Cholesterol Test strip and the LipidPro® Professional HDL-cholesterol Test Strip are used to measure total cholesterol (TC) and high density lipoprotein cholesterol (HDL-C) in capillary whole blood respectively and the measurements obtained are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid, and lipoprotein metabolism disorders.The LipidPro® Professional Total Cholesterol Test strip and LipidPro® Professional HDL-cholesterol Test Strip measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. The LipidPro® Professional Triglyceride Test Strip is used to measure triglyceride (TG) in capillary whole blood and the obtained measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism, or various endocrine disorders. Calculated LDL-cholesterol values are reported only when triglycerides are ≤ 350 mg/dL; when triglycerides are > 350 mg/dL, calculated LDL-cholesterol are not reported.
The LipidPro® Professional Lipid Profile Test Strip is used to measure TC, HDL-C, and TG in capillary whole blood at the same time.
The LipidPro® Professional Glucose Test Strip is for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients as an aid in the management of diabetes. Glucose measurement is not to be used for the diagnosis of or screening for diabetes and/or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

The LipidPro® Professional Total Cholesterol Control Solution, HDL-cholesterol Control Solution, Triglycerides Control Solution, and Glucose Control Solution are used to test the precision of the LipidPro® Professional Lipid Profile and Glucose Measuring System and to detect systematic analytic deviations that may arise from reagent or analytical variation and they are for testing outside the body (in vitro diagnostic use only).The LipidPro® Professional Control Solutions are intended for use in hospital and professional health care settings.

7. Comparison to the Cleared Device

The modifications to the cleared device are as follows: adding strip error message, strip code error message and a check strip, changing the button utilized to enter memory mode, modifying the design of the strip cover(all five strips) and the capillary rod, changing the raw material of control solution bottles, adding foil pouch package option for the strips(for the LipidPro® Total Cholesterol Test Strip, LipidPro® HDL-cholesterol Test Strip, LipidPro® Triglyceride Test Strip, and LipidPro® Lipid Profile Test Strip), adding printing option and printing / data transfer to PC

error message and display temperature unit change.

Other than these modifications, the modified system has the following similarities to the cleared device:

- has the same intended use,
- uses the same operating principle,
- incorporates the same materials,
- adopts the same use environment and calibration method, and has the same shelf life.

8. Performance Data

Clinical & Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the LipidPro® / LipidPro® Professional Lipid Profile and Glucose Measuring System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

Disinfection Study: Disinfectant CaviWipes with the EPA registration number of 46781-8 has been

validated demonstrating complete inactivation of live virus of use with the meter and the reusable lancing device. There was also no change in performance or in the external materials of the meter and the lancing device after 10,980 cleaning/disinfection cycles designed to simulate 3 years of device use.

9. Conclusion

The conclusion drawn from the clinical and nonclinical tests is that the the LipidPro® / LipidPro® Professional Lipid Profile and Glucose Measuring System is as safe, as effective and performs as well as the legally marketed predicate device, LipidPro™ System (K090405).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 21, 2013

Infopia Co., Ltd.
C/O Priscilla Chung
LK Consulting Group
1515 E Katella Ave., Unit 2115
ANAHEIM CA 92805

Re: K130295
Trade/Device Name: LipidPro® Lipid Profile and Glucose Measuring System
LipidPro® Professional Lipid Profile and Glucose Measuring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, CHH, JGY, JJX, LBR
Dated: May 17, 2013
Received: May 22, 2013

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K130295

Device Name: LipidPro® Lipid Profile and Glucose Measuring System

Indication for use:

The LipidPro® Lipid Profile and Glucose Measuring System is intended for self testing (in home) and for testing outside the body (in vitro diagnostic use only). The LipidPro® Lipid Profile and Glucose Measuring System, which consists of a meter and test strips, measures total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG) and glucose in capillary whole blood. The LipidPro® Lipid Profile and Glucose Measuring System is intended to be used by a single patient and should not be shared.

The LipidPro® Total Cholesterol Test Strip, LipidPro® HDL-cholesterol Test Strip, LipidPro® Triglyceride Test Strip, LipidPro® Lipid Profile Test Strip, and LipidPro® Glucose Test Strip are for use with the LipidPro® Lipid Profile and Glucose Meter.
The LipidPro® Total Cholesterol Test Strip and the LipidPro® HDL-cholesterol Test Strip are used to measure total cholesterol (TC) and high density lipoprotein cholesterol (HDL-C) in capillary whole blood respectively and the measurements obtained are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid, and lipoprotein metabolism disorders. The LipidPro® Total Cholesterol Test Strip and LipidPro® HDL-cholesterol Test Strip measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. The LipidPro® Triglyceride Test Strip is used to measure triglyceride (TG) in capillary whole bloodandthe obtained measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism, or various endocrine disorders. Calculated LDL-cholesterol values are reported only when triglycerides are ≤ 350 mg/dL; when triglycerides are > 350 mg/dL, calculated LDL-cholesterol are not reported.
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The LipidPro® Glucose Test Strip is for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients as an aid in the management of diabetes. Glucose measurement is not to be used for the diagnosis of or screening for diabetes and/or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

LipidPro® Total Cholesterol Control Solution, HDL-cholesterol Control Solution, Triglycerides Control Solution, and Glucose Control Solution are used to test the precision of the LipidPro® Lipid Profile and Glucose Measuring System and to detect systematic analytic deviations that may arise from reagent or analytical variation and they are for testing outside the body (in vitro diagnostic use only). LipidPro® Control Solutions are intended for use in home.

Prescription Use _____	AND/OR	Over-The-Counter Use ✓
(Part 21CFR 801Subpart D)		(Part 21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OFNEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) k130295

Indications for Use

510(k) Number: K130295

Device Name: LipidPro® Professional Lipid Profile and Glucose Measuring System

Indication for use:

The LipidPro® Professional Lipid Profile and Glucose Measuring Systemis intended for multiple patient use in professional health care settings and for testing outside the body (in vitro diagnostic use only). The LipidPro® Professional Lipid Profile and Glucose Measuring System which consists of meter and test strips, measures total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG), and glucose in capillary whole blood. The LipidPro® Professional Lipid Profile and Glucose Measuring System should only be used with auto-disabling, single-use lancing device.

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Prescription Use ✓ (Part 21CFR 801Subpart D) AND/OR Over-The-Counter Use ✓ (Part 21CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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